

REMARKS

With the present communication, no claims are amended, added, or canceled. Claims 1-21 and 26-27 are pending in this application, with claims 26-27 under examination. Applicants respectfully request reconsideration of the application for the reasons that follow.

Claim Rejections – 35 USC § 102

Claims 26 and 27 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,897,426 to Llinas, *et al.*, (“Llinas”). Llinas teaches methods of blocking calcium low-threshold channels comprising the administration of aliphatic alcohols. Llinas at abstract. The Examiner asserts that Llinas teaches the administration of octanol to cells or mammalian subjects at concentrations that “coincide with the range shown in the specification to modulate cholesterol levels,” and that Llinas teaches administering octanol to a mammal in sufficient quantities to generate a blood concentration “of up to 1 mM.” Office Action , p. 2. The Examiner asserts that Llinas teaches each of the steps of the pending claims, and that the Llinas methods “would be expected to increase or decrease cellular cholesterol levels as recited in the instant claims,” such that “Llinas inherently anticipates the pending claims.” *Id.* at p. 2-3. Applicants traverse the rejection for the reasons that follow.

The pending claims are drawn to methods of modulating a cholesterol level of a cell comprising contacting one or more cells with an effective amount of octanol, or octanol and one or more of ceramide, diglyceride and lysophosphosphatidyl choline, thereby increasing or decreasing the cholesterol level of the one or more cells. In some embodiments, the one or more cells are *in vivo*.

As stated in the M.P.E.P., “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131, *quoting Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). If the alleged anticipation is based on inherency, it must be supported by a rationale or evidence tending to show inherency. To establish inherency, “the extrinsic evidence

‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robinson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added; internal citations omitted). In this case, the Examiner has not met the evidentiary burden for a rejection based on inherency, and has mischaracterized the teachings of the prior art.

The Examiner has cited no evidence that the missing subject matter is necessarily present in the cited art or that it would be so recognized by one of ordinary skill in the art. Rather, the Examiner has assumed that the Llinas methods would inherently modulate cholesterol levels based solely on the use of octanol. In the Examiner’s own words, “the method of Llinas would be expected to increase or decrease cellular cholesterol levels as recited in the instant claims.” Office Action, p. 3 (emphasis added). This does not meet the standard for a showing of inherency.

The Examiner has also misapprehended the teachings of Llinas with respect to the concentration of octanol disclosed. Llinas teaches the administration of octanol in sufficient quantities to generate a blood concentration of 1 uM (10^{-6} M), *not* 1 mM (10^{-3} M) as the Examiner asserts. Examples 3 and 4 of the present application state that cholesterol modulation was measured in response to 0.2-0.8 mM octanol, which is a 200-800 fold higher concentration than disclosed in Llinas. Application, p. 17, Fig. 4. Llinas clearly states at Table 1, col. 7, that the “[p]referred highest molar concentration[s]” of octanol for use in the disclosed methods is “ 10^{-6} M.” Because the concentrations of octanol disclosed in Llinas are substantially lower than those of the present application, there is *no basis* to conclude that the Llinas methods would necessarily result in modulation of cholesterol levels.

Because the Examiner has not met the burden for an inherency rejection and has mischaracterized the teachings of the cited reference, this claim rejection is improper. Accordingly, Applicants request that the rejection be withdrawn.

Conclusion

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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